K060535

MAY 24 2006

# Tecres Spacer-S

## Traditional 510(k)

## Summary of Safety and Effectiveness

**Date:** May 24, 2006

**Applicant/Consultant:**
Exactech® Inc.
2320 N.W. 66th Court
Gainesville, Florida 32653
Phone: (352) - 377 - 1140
Fax: (352) - 378 - 2617
Contact: Gary J. Miller, PH.D.
Exec. V.P. of R&D

**Manufacturer:**
Tecres S.p.A
FDA Owner/Operator ID# 9033624

**Classifications / Proprietary Names:**

| | |
|---|---|
| Trade / Proprietary Model Names: | Spacer-S<br>Temporary Shoulder Prosthesis |
| Common name: | Shoulder spacer |
| Classification Name: | Prosthesis, Shoulder, Hemi-, Humeral, Metallic, Cemented or Uncemented |
| Device Class: | II |
| Classification Panel: | Orthopedic |
| Product Code: | HSD |
| C.F.R. Section: | 888.3690 |

**Device Description**
Spacer-S is composed of fully formed gentamicin/polymethylmethacrylate (PMMA) bone cement. The one piece design mimics a hemi-shoulder prosthesis.

**Intended Use**
Spacer-S is intended for use as a temporary (maximum 180 days) shoulder replacement in patients undergoing a two-stage procedure due to a septic process.

The device is intended for use in conjunction with systemic antimicrobial antibiotic therapy (standard treatment approach to an infection) as defined by physician and/or surgeon.

**Substantial Equivalence:**
Based on a comparison of design features and the results of performance testing, it is concluded that the Spacer-S device is substantially equivalent functionally to the predicate Equinoxe Shoulder System device (#K042021). Whereas the Spacer-S device differs technologically from the predicate, the differences do not raise new questions of safety and effectiveness. In conclusion, the Spacer-S as a temporary shoulder prosthesis raises no new issues of safety and effectiveness considering the recommended duration of implantation for the Spacer-S.

**Performance data**
Performance testing was conducted to verify that the implant performance would be adequate for anticipated *in vivo* load applications under the temporary conditions of use. The fatigue strength, static strength, and antibiotic release were evaluated and found to support the substantial equivalence of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 24 2006

Exactech, Inc.
c/o Ms. Diana Taylor
Manager, Regulatory Affairs
2320 NW 66th Court
Gainesville, Florida 32653

Re: K060535
Trade/Device Name: Tecres Spacer-S
Regulation Number: 21 CFR 888.3690
Regulation Name: Shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis
Regulatory Class: Class II
Product Code: HSD, KWS
Dated: February 27, 2006
Received: February 28, 2006

Dear Ms. Taylor:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Mark N. Melkerson
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

**Tecres Spacer-S**

**Traditional 510(k)**

**Indications for Use**

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**510(k) Number:** K060535

**Device Name:** **Tecres Spacer-S**

**Indication for Use**

Spacer-S is indicated for temporary use (maximum 180 days) as an adjunct to total shoulder replacement and hemi shoulder replacement procedures in skeletally mature patients undergoing a two-stage revision procedure due to a septic process. Spacer-S is only indicated for an implantation period of 180 days or less.

Please do not write below this line - use another page if needed.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X Over the Counter Use No

**(Division Sign-Off)**
**Division of General, Restorative, and Neurological Devices**

**510(k) Number** K060535